

GLUTEN

Guidelines for Implementing Gluten-Free Labeling of Foods 2013



As part of the Federal Food Allergen Labeling Consumer Protection Act of 2004 (FALCPA), the United States Food and Drug Administration (FDA) was instructed to develop a regulatory definition of “gluten free” and related terms. The Final Rule was published on August 5, 2013 in the Federal Register and became effective on September 4, 2013. Food processors must comply with the Final Rule by August 5, 2014.



Background

Gluten is the naturally occurring storage protein of grains such as wheat, rye, barley and their crossbreeds. Most people can consume foods containing gluten without any adverse reactions; however, as many as 3 million people in the United States suffer from celiac disease. In those individuals, gluten causes their immune system to attack the lining of the small intestine. The resulting inflammation can hinder the body’s ability to properly absorb some nutrients and lead to conditions such as anemia, osteoporosis, diabetes, autoimmune thyroid disease, and intestinal cancers. There is no cure for celiac disease so individuals with the condition must carefully avoid the protein.

Major Provisions of the Final Rule

Several provisions are outlined in the Final Rule, including:

- A. In order to be labeled as “gluten free,” a food must contain less than 20 parts per million (ppm) of gluten.
- B. Any food labeled as “gluten free,” “no gluten,” “free of gluten,” or “without gluten” must not contain 20 ppm or more of gluten. Foods exceeding that limit and labeled as such are considered misbranded.
- C. Use of the term “gluten free” is voluntary. A food which contains less than 20ppm of gluten is not required to be labeled as “gluten free.”
- D. Foods which do not naturally contain gluten (e.g. raw carrots, grapefruit juice, etc.) may use the “gluten free” claim.
- E. Food manufacturers must comply with the Final Rule by August 5, 2014.

Additional Information

- 1. CDPH – Food and Drug Branch, Food Safety Program Information
<http://www.cdph.ca.gov/programs/Pages/FDB%20Food%20Safety%20Program.aspx>
- 2. Final Rule from Federal Register
<https://www.federalregister.gov/articles/2013/08/05/2013-18813/food-labeling-gluten-free-labeling-of-foods#h-26>
- 3. FDA – Gluten-Free Labeling of Foods Guidance Document
<http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Allergens/ucm362510.htm>